Remarks/Arguments:

This response does not add, cancel, or amend any claims. Accordingly, in doing so, no new matter has been added. Upon entry of this response, claims 1-6 will be pending, wherein claims 1-3 are independent.

Rejections of the Claims under 35 U.S.C. 103

The Examiner has maintained the rejection of claims 1-6 under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent Publication No. 2002/0055711 of Lavi et al. (hereinafter Lavi) in view of U.S. Patent No. 5,976,111 of Hart (hereinafter Hart).

Specifically, the Examiner points to Lavi as disclosing a device for delivering a medicament having a housing with a top surface, a bottom surface adapted to contact a skin surface of a patient, a reservoir, and an injection needle adapted for penetration of the skin surface and for movement through a needle aperture.

The Examiner further points to Lavi as disclosing such a device having a safety member adapted for movement away from the bottom surface of the housing, having a first position wherein the shield of said safety member is initially disposed within the housing and a second position wherein the shield is at least partially withdrawn from the housing and at least partially covers the injection needle.

The Examiner further points to Lavi as disclosing such a device having a spring element configured to bias the shield and covering portion of the safety member toward the second position and a rotatable door disposed upon the bottom surface of the housing, having a first position which prevents movement of the safety member, and a second position which allows movement of the safety member, wherein when the device is placed upon the skin surface of the patient and activated, the rotatable door is released and free to rotate from the first position to the second position and the spring element is free to urge the safety member into the second position, whereby, as the device is removed from the skin surface, the shield of the safety member emerges from the housing and at least partially covers the injection needle.

The Examiner finally points to Hart as disclosing such a device further having a reservoir disposed within the housing in fluid communication with the injection needle, such that the combination of the Lavi and Hart references purportedly renders obvious the device as recited by the Applicants in claim 1.

As noted by the Examiner, the Lavi reference does not describe a reservoir disposed within the alleged housing of elements 210 and 220, and simply describes the provision of a drug delivery port 274 that communicates with a needle chamber 275 (see Figs. 20A-20C). The port 274 is formed through an arm 273 that extends radially from an enlarged flange portion 272 of the needle holder 270 (see paragraph 123).

Accordingly, the Examiner points to Hart as disclosing such a reservoir disposed within the housing in fluid communication with the injection needle. Specifically, the Examiner points to the syringe 10 of Hart as constituting a reservoir disposed within a housing as recited by the Applicants.

The Hart reference describes the provision of an auto-positioned needle guard for a syringe (see Abstract). In this case, the syringe is simply provided to illustrate how the needle guard operates, and any syringe can be used to show the same or similar features. Accordingly, the Applicants assert that the provision of a syringe 10 in Hart, even if coupled with the drug delivery port 274 of arm 273 of Lavi, does not constitute a reservoir as recited by the Applicants, and more specifically, does not constitute a reservoir disposed within a housing with top and bottom surfaces as recited by the Applicants. That is, even where the syringe 10 is provided, it is not disposed within a housing allegedly described by elements 210 and 220 of Lavi, nor would it have been obvious to do so, but would be coupled externally to the housing allegedly described by elements 210 and 220 of Lavi.

In response, the Examiner asserts that "the syringe body (10 of Hart) would be included as part of the device and as such the reservoir is within the housing". The Examiner further asserts that it would be obvious to use the syringe 10 of Hart with the needle device of Lavi. However, in this case, in order to describe the syringe as a reservoir as recited by the Applicants, the syringe 10 of Hart would be required to be attached or otherwise disposed within a housing allegedly described by the elements 210 and 220 of

Lavi. However, the syringe 10 of Hart would connect with the port of arm 273 (see Lavi Fig. 20A), or port of arm 46 (see Lavi Fig. 1, paragraph 83) as noted by the Examiner. In each case, 46 and 273 *extend* from the alleged housing of the device of Lavi, therefore, even when the syringe 10 of Hart is connected with the device of Lavi, it would be *outside the housing* allegedly described by the elements 210 and 220 of Lavi. No reservoir is described within any housing described by the elements 210 and 220 of Lavi even in combination with the syringe 10 of Hart and at most, the addition of Hart describes a syringe 10 connectable externally thereto via ports of arms 46 or 273. Accordingly, the combination of Lavi and Hart fail to describe a reservoir, even in the case of an attached syringe, within a housing allegedly described by the elements 210 and 220 of Lavi.

Regarding the safety member, the Examiner points to Lavi as disclosing a safety member, biasing spring element, and rotatable door disposed on the bottom surface of the housing as recited. Specifically, the Examiner points to the latches 237 of Lavi Figs. 18-20 as constituting such a rotatable door. The latches 237 of Lavi are configured to be pushed free by downward travel of element 270, to thereby allow the guard 231 to be pushed as urged by spring 232.

However, in doing so, the latches which allegedly constitute the rotatable door, are *entirely contained within the device.* In contrast, the Applicants describe a system and method wherein the rotatable door is disposed on the bottom surface, and the bottom surface is configured to contact the skin surface. As such, the rotatable door as recited is disposed differently than the latches 237 of Lavi.

In response, the Examiner asserts that the Applicants do not recite orientation of the rotatable door with respect to the bottom surface and as such, the latches 237 of the needle shield 231 of Lavi, describe such a rotatable door disposed on the bottom surface, and the bottom surface is configured to contact the skin surface. The Applicants disagree and note that the claim recites a bottom *surface* is configured to contact the skin surface, and a rotatable door *disposed* on the bottom *surface.* No door nor latches 237 are disposed on the bottom *surface* of Lavi, rotatable or otherwise, and latches 237 are positioned *within* the

device, and are simply part of a needle shield 231 which has a bottom surface. However, nothing is disposed upon the bottom surface of the needle shield 231.

Further, where element 210 of Lavi allegedly describes a bottom surface of the housing as argued by the Examiner, no rotatable door nor latches 237 are disposed on the bottom *surface* of element 210 of Lavi.

The Examiner has also maintained the rejection of claims 2 and 5 under 35 U.S.C. 103(a) as allegedly being unpatentable over Lavi in view of Hart.

In regard to independent claim 2, the Applicants recite a housing with a top surface, a bottom surface adapted to contact a skin surface of a patient, a reservoir, and an injection needle adapted for penetration of the skin surface and for movement through a needle aperture as in claim 1, and further recite a safety member adapted for linear movement substantially perpendicular to the bottom surface of the housing, having a skin contacting portion and at least one shield protruding from the skin contacting portion and configured to be held in place by a device activation button. The safety member has a first position initially disposed within the housing and held in place by the device activation button, and a second position wherein the shield of the safety member is released by activation of the device activation button and is at least partially withdrawn from the housing and at least partially covers the injection needle.

The Examiner points to Hart as disclosing such a reservoir disposed within the housing in fluid communication with the injection needle. However, as noted above, the combination of Lavi and Hart fails to describe a reservoir, even in the case of an attached syringe, within a housing allegedly described by the elements 210 and 220 of Lavi. No reservoir is described within any housing described by the elements 210 and 220 of Lavi even in combination with the syringe 10 of Hart, and at most, the addition of Hart describes a syringe 10 connectable externally thereto via 46 or 273. Accordingly, the combination of Lavi and Hart fail to describe a reservoir, even in the case of an attached syringe, within a housing allegedly described by the elements 210 and 220 of Lavi.

Further, the Applicants recite a safety member held in place by the device activation button, and released by activation of the device activation button. However, the shield 231 of Lavi is held in place by the latches 237 sitting on the top of the needle hub (see Fig. 17 and paragraph 127). That is, the shield 231 of Lavi is held from activation by interference with the needle hub, and not by an activation button. Even where an activation button can be used to allegedly release the shield 231 of Lavi, the shield is not held from activation by the activation button.

The Examiner has also maintained the rejection of claims 3 and 4 under 35 U.S.C. 103(a) as allegedly being unpatentable over Lavi in view of Hart.

In regard to independent claim 3, the Applicants recite a housing with a top surface, a bottom surface, a reservoir, and an injection needle adapted for penetration of the skin surface and for movement through a needle aperture as in claim 1, and further recite a safety member adapted for rotational movement along an arcuate path relative to the bottom surface of the housing, having a skin contacting portion and a pivot, the safety member having a securing means while in a first position wherein the safety member is secured against the bottom surface and substantially co-planar with the bottom surface of the housing, and a second position wherein the safety member is released and rotated about the pivot and at least partially covers the injection needle.

The Examiner points to Hart as disclosing such a reservoir disposed within the housing in fluid communication with the injection needle. However, as noted above, the combination of Lavi and Hart fails to describe a reservoir, even in the case of an attached syringe, within a housing allegedly described by the elements 210 and 220 of Lavi. No reservoir is described within any housing described by the elements 210 and 220 of Lavi even in combination with the syringe 10 of Hart and at most, the addition of Hart describes a syringe 10 connectable externally thereto via 46 or 273. Accordingly, the combination of Lavi and Hart fail to describe a reservoir, even in the case of an attached syringe, within a housing allegedly described by the elements 210 and 220 of Lavi.

Further, the Applicants recite a safety member adapted for rotational movement along an arcuate path relative to the bottom surface of the housing, having a securing means while in a first position wherein the safety member is secured against the bottom surface and substantially co-planar with the bottom surface of the housing, and a second position wherein the safety member is released and rotated about the pivot and at least partially covers the injection needle.

However, the Applicants assert that the shield 231 of Lavi does not rotate and more specifically, does not rotate along an arcuate path relative to the bottom surface. Further, the deflectable latches 237 which may allegedly rotate, also do not rotate along an arcuate path relative to the bottom surface and even where such rotation allegedly occurs, such rotation of the safety member does not occur about the pivot from the first position to the second position. That is, the rotation of the deflectable latches 237 does not place the safety member into the second position (see Lavi Fig. 19 which shows the deflected latches 237 without movement of the latches or shield to a second position as recited by the Applicants).

The Examiner has also maintained the rejection of claims 3 and 4 under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,500,150 of Gross et al. (hereinafter Gross 1) in view of U.S. Patent No. 5,997,501 of Gross et al. (hereinafter Gross 2).

Specifically, the Examiner points to Gross 1 as disclosing a device for delivering a medicament having a housing with a top surface, a bottom surface, and an injection needle adapted for penetration of the skin surface and for movement through a needle aperture.

The Examiner also points to Gross 1 as disclosing such a device further having a reservoir disposed within the housing in fluid communication with the injection needle, and a safety member adapted for rotational movement along an arcuate path relative to the bottom surface of the housing, and having a skin contacting portion disposed about the needle aperture and substantially covered with adhesive, and a pivot, such that the safety member has a first position wherein the safety member is substantially co-planar with the bottom

surface of the housing, and a second position wherein the safety member is rotated about the pivot and the safety member at least partially covers the injection needle.

The Examiner also points to Gross 1 as disclosing such a safety member wherein when the device is placed upon the skin surface of the patient, the skin contacting portion of the safety member is temporarily adhered to the skin surface, and when the device is removed from the skin surface, the adhesion of the safety member to the skin surface is sufficient to rotate the safety member about the pivot from the first position to the second position.

The Examiner points to Gross 2 as disclosing such a safety member having a securing means while in the first position such that the safety member is secured against and substantially co-planar with the bottom surface of the housing in the first position, such as in a pre-use position, and released by activation of the device.

In the Applicants' disclosure, a securing means can be achieved through the use of, for example, the door 790 and door latch 791 of Fig. 39 (see also paragraph 319), and the lock arm 1034 of Fig. 123 (see also paragraph 342). In this case, the device can be positioned against a skin surface, and activation movement of the push button releases the latch or lock arm. However, as the device is adhesively positioned against a user's skin, no movement of the safety member is allowed, but the safety member is free to move upon removal of the device. In doing so, the Applicants recite a system and method wherein the safety member has a securing means while in the first position such that the safety member is secured against and substantially co-planar with the bottom surface of the housing, such as in a pre-use position, and released by activation of the device. If the device is not properly activated, the safety member cannot be inadvertently deployed, even if adhesion somehow occurs.

The Gross 2 reference describes a protective displaceable cover 303 which can be coated with an adhesive to be pulled by a skin contact surface to an extended position. A resistance to such movement is provided by the rounded projections at ends thereof and which are displaced in notches 305 and 306 (see Figs. 15 and 16, and col. 13, lines 25-35).

However, there is no disclosure in Gross 2 that the projections are released from the notches 305 or 306 by activation of the device. That is, the notches and detents of Gross 2

are simply provided to hold a retracted or extended position of the cover 303 against minimal resistance. In contrast, the Applicants recite a system and method wherein activation of the device releases the securing means, and adhesion with the skin surface rotates the released safety member. Specifically, the Applicants recite that the securing means is released by activation of the device such that when the device is removed from said skin surface, adhesion of the safety member to the skin surface is permitted to rotate the safety member.

In response, the Examiner asserts that the Applicants do not recite any limitation as to what constitutes device activation, and that any device manipulation therefore can describe device activation, allegedly including removal of the device which appears to pull the detents of the guard 303 down and into recesses 305. In Gross 2, it appears that the pressing downward of the device pushes the guard 303 and detents up and into recesses 306 (see Figs. 13-14), and the removal of the device from the skin surface pulls the guard 303 and detents down and into recesses 305 (see Figs. 15-16, and Abstract).

However, the Applicants describe a system and method wherein the securing means is *released by activation* of the device, and the safety member is *rotated (moved) by adhesion* of the safety member to the skin surface. The Gross 2 reference describes the alleged *release of the guard by adhesion*, and not by any activation. At most, in the case where activation is the pushing down of the device (see again Figs. 13-14), the guard 303 is released, but into an opposite position than recited by the Applicants (i.e., not secured against a bottom surface). In the case where activation is also the pulling up of the device from the skin (see again Figs. 15-16), the *adhesion with the skin surface* is the force releasing the guard 303.

As such, as the Applicants *separately recite* activation of the device, and adhesion with the skin surface, as two separate forces used by the device, the activation force is different than the adhesion force. The Applicants recite the release via an activation force, not the adhesion force, which is the alleged releasing force in Gross 2.

Accordingly, for at least these reasons, the Applicants assert that the Lavi, Hart, Gross 1 and Gross 2 references, separately or in combination, do not disclose or reasonably suggest

each element as recited in independent claims 1, 2 and 3, and respectfully request the withdrawal of the rejection under 35 U.S.C. 103(a). Dependent claims 4, 5 and 6 which are dependent from claims 1, 2 and 3, are allowable for at least these reasons.

Conclusion

In view of the above, it is believed that the application is in condition for allowance and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

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